Remarks and Response

Remarks

Applicant appreciates the Examiner's efforts as described in the Interview Summary to get the prosecution of this matter back on track after it appears to have lost for 16 months at the USPTO, and Applicant's representative will provide any document requested by the Examiner to replace documents that are missing from the record file. Claims 33-41 and 45-64 are pending in this matter. Non-elected claims submitted in the original filing are, or will be, the subject of Divisional filings, without prejudice to the invention as a whole. Previously pending claims 33-84 have now been amended, claims 42-44 and claims 65-84 cancelled, and new claims 201-249 added – thereby separating i) the method of creating data associated with a product or device, wherein the method comprises accessing at least one adverse event data source comprising previously gathered adverse event data associated with a product or device; analyzing such adverse event data to identify new essential adverse events associated with the product or device; and creating at least one essential adverse event information database; from ii) a method for using data associated with at least one database, wherein essential adverse event information is stored as defined, said method comprising accessing the essential adverse event information database and in a novel manner, commercializing essential adverse event information stored therein.

Support for each new claim 201-249 may be found, however, in originally filed claims 33-84. No new matter has been added.

Response

Regarding Rejection under 35 U.S.C. §112, 1st

The Examiner has rejected claims 33-84 under 35 U.S.C. §112, 1st as allegedly failing to meet the enablement requirement. The rejection is traversed for the following reasons.

The Examiner has rejected the recitation in the method of claim 33 of the step of "analyzing the adverse event data to identify new essential adverse events associated with the product or device." In making this argument, the Examiner states that "the manner and process of making new essential adverse events is not clearly and concisely described in the specifications" and cites paragraph 0068 as containing the most relevant information in the specification.

Such a conclusion is unfairly restrictive to Applicant, because as set forth in the specification, the invention is far broader than that which is condensed into paragraph 0068. Applicant's instant invention is related to, and an improvement over, US Pat. Nos. 6,219,674 and 6, 584,472 (US Ser. No. 09/804,289), both of which are expressly incorporated by reference in the specification (paragraph 0003). Improved methods are patentable subject mater. Thus, the incorporated patents, by their reference, provide one skilled in the art with additional information, which has previously been published and need not be reiterated in the pending Application.

However, contrary to the limitations found in the prior art, the pending application provides an improved method, in at least claim 33, by identifying *new* "essential" adverse event information, as opposed to the prior art methods, which searched for any new adverse event. As defined in the specification, one is taught in at least paragraphs 0004, 0086 and 0087, how to identify "essential" information. Moreover, one skilled in the art of the present invention would also be familiar with the definition of essential adverse event information, as set forth in the current United States Code of Federal Regulations (21 C.F.R. 201.57). See Exhibit A attached hereto.

It has been consistently held that the first paragraph of 35 U.S.C. 112 requires nothing more than objective enablement. *In re Marzocchi*, 169 USPQ 367 (CCPA 1971). In satisfying the enablement requirement, an application need not teach, and preferably omits, that which is well known in the art. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81 (Fed. Cir. 1986).

As Applicant has stated in the specification, "the government has carefully established codes and rules under which, for example in the medical field, manufacturers and/or distributors are required to notify or warn the public of known adverse events which could occur when certain products, including drugs, medicaments and the like, are ingested or used by human or veterinary patients." See specification paragraph 0004. The final determination of what is "essential" information is determined by a regulatory agency such as the FDA. See paragraph 0086. Thus, one skilled in this art would readily turn to the FDA to learn what is meant by "essential information." Moreover, as stated at paragraph 0087, "New adverse event information that is "essential" is of great commercial value since if this information is proprietary, for example patented in the form a new use, it can be used to exclude potential competitors from

selling a product which would require the essential information. In order for a company searching through raw adverse new uses, to maximize profits from such a search, the "essential" new uses should ideally be separated from other new uses. By limiting the protection for such new data, *e.g.*, patenting, and limiting petitions to regulatory agencies to only the "essential" new uses, a company saves time and money by avoiding expending time on adverse event information that has little commercial value."

The Examiner then continues to explain that what is needed to satisfy the written description requirement in a patent specification, and states that Applicant's reference to "any other analysis of raw data" demonstrates that the applicant did not have possession of the invention at the filing date. Apparently, the Examiner confuses the *enablement requirement* under which the rejection was made, with the *written description requirement* – which is distinct and not encompassed by the Examiner's stated rejection under 35 U.S.C. §112, 1st. "Enablement" requires that the application "contain a description that enables one skilled in the art to make and use the claimed invention," citing *Atlas Powder Co. v. E.I. duPont de Nemours & Co.*, 224 USPQ 409, 413 (Fed. Cir. 1984). Thus, the "written description" requirement of 35 U.S.C. 112 is separate from the "enablement" requirement; in that an invention may be described without the disclosure being enabling. See *Gosteli v. McCombie*, 230 USPQ 205, 209 (BPAI 1986). The test for adequacy of the written description is whether the disclosure of the application relied upon reasonably conveys to a person skilled in the art that the inventor had possession of the claimed subject matter at the time of the earlier filing date. See, *Ralston Purina Co. v. Far Mar Co, Inc.*, 227 USPQ 177, 179 (Fed. Cir. 1985). "Teaching how to make and use an invention" and "a required demonstration of possession of the claimed subject matter at the time of the earlier filing date" are separate and distinct concepts that cannot be combined into a single rejection for the convenience of the Office.

Nevertheless, according to *Ex parte Obukowicz*, 27 USPQ2d 1063, 1067 (Bd. Pat. App. & Int. 1992) "[i]t is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art." Therefore, in making this rejection, the Examiner erroneously suggests that the invention set forth in claim 33, must be limited to only a single exemplified species, and cannot broaden the invention to include other analyses of raw data that would also be encompassed by the scope of the invention. To the contrary, Applicant's use of illustrative examples and broad descriptive terminology in the disclosure that

correspond in scope to the claims adequately meets the requirement that "only objective enablement without resort to undue experimentation is required." *Staehelin v. Secher*, 24 USPQ2d 1513, 1518 (BPAI 1992). Consequently, unless the Examiner can demonstrate a supported basis, beyond his own conclusions, for doubting the objective truth of statements made in Applicant's specification for enabling support, Applicant's claims must be considered to be compliant with the enablement requirement. The law does not require a specification to be a blueprint in order to satisfy the requirement for enablement under 35 U.S.C. 112, 1st paragraph.

The Examiner further states with regard to claim 33, that "[t]hose skilled in the art would not be able to make and use the invention because the manner and process of making a new useful characteristic or use for the product or device is not clearly and concisely described in the specification" and as a result, the Examiner concludes that one skilled in the art would not be able to make and use the product. However, the Examiner offers no support for such a conclusion in response to that statement.

To the contrary, Applicant contends that one skilled in the art, after reading the specifications, would know that a "new use" based on the adverse event is simply a use that involves avoid giving the product to the high risk group or providing instructions to the user that the there is a group where the risk is very high, such as those eating a specific food. "Patents are written to enable those skilled in the art to practice the invention, not the public" (*W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 USPQ 303, 315 (Fed. Cir. 1983)), and contrary to the Examiner's conclusion, such an individual would understand what is meant in Applicant's specification.

The Examiner states that with regard to claim 44 "wherein commercializing further comprises formatting the data relating to at least one new adverse event associated with exposure to, or use of the product or device, or documenting same, such that a manufacturer or distributor of the product or device must inform consumers, users or individuals responsible for the user, physicians or prescribers about at least one new adverse event associated with exposure to or use of the product or device" – and as a result the Examiner concludes that one skilled in the art would not be able to make and use the product. However, the Examiner offers no support for such a conclusion.

To the contrary, Applicant contends that one skilled in this art would be an individual practiced in the field of regulatory affairs, particularly with regard to practices in the

pharmaceutical industry, and would include individuals who regularly submit adverse events on a drug to the FDA. One skilled in this art would know of, and be familiar with, "Requirements for reporting adverse events to the FDA and including these on package labeling" (Exhibit A, 21 C.F.R. 201.57, referenced above). Moreover, additional explanation is incorporated in the pending application by reference to US Pat. Nos. 6,219,674 and 6, 584,472, which information need not be restated because it is part of the prior art.

Regarding claim 68, the Examiner states that "wherein at least one new adverse event is based upon neither a drug interaction, nor a chronic immune mediated disorder" – and as a result, the Examiner concludes that one skilled in the art would not be able to make and use the product. However, the Examiner offers no support for such a conclusion.

To the contrary, Applicant contends that one skilled in this art would, indeed, be able to make and use the invention. The level of skill needed in this are is as defined above, and as a result, such an individual would know of attached Exhibit A, in which it is taught that "an adverse event other than a drug interaction or a chronic immune mediated disorder could include an heart attack, a seizure, or kidney failure as described below." Moreover, as previously explained, the information provided in the specification does not exist in a vacuum. Rather, information provided by US Pat. Nos. 6,219,674 and 6, 584,472 is incorporated by reference and need not be reiterated since it is readily found in the prior art. See specification, for example, at least, at paragraphs 0036, 0043 and 0051.

The Examiner states that with regard to claim 76 that "using the method to develop at least one essential proprietary new method of screening a product or device for safety" – and as a result, the Examiner concludes that one skilled in the art would not be able to make and use the product. However, the Examiner offers no support for such a conclusion.

To the contrary, Applicant contends that one skilled in this art be able to make and use the invention, and would understand exactly what is meant in this claim. In essence, the claim defines the invention as one in which, after the practitioner performs an epidemiological study on a drug and then finds patentable adverse event information, that one also patents the method used to detect the adverse event. For example, one could claim a safer method of testing drug X for adverse events by steps A, B and C, wherein A, B, C define the method used to find the crucial adverse event information. Support may be found for such a claim at least in paragraphs 0100, 0101 and 0102.

Accordingly, in light of the foregoing arguments, Applicant respectfully asks that the rejection under 35 U.S.C. §112, 1st paragraph be withdrawn and the claims, as well as all claims dependent thereon, be found enabling, and that the application be advanced to allowance.

No art rejection for claims 44, 68 and 76

The Examiner has found no art that presently establishes a basis for rejecting claims 44, 68 or 76. Therefore, presumably, if the above discussed rejection of those claims under 35 U.S.C. §112, 1st paragraph is overcome and withdrawn, claims 44, 68 and 76 would be found to be patentable. Accordingly, Applicant seeks to have those claims declared patentable.

Regarding rejections under 35 U.S.C. §102

The Examiner has rejected claims 33-36, 38-40, 48-51, 56, 57 and 64 under 35 U.S.C. §102(e), as being anticipated by US Pub No. 2001/0001144 (Kapp). In making this rejection, the Examiner lists on page 8 of the Office Action, the steps that Kapp allegedly teaches, and compares them to the steps taught by Applicant, concluding that they anticipate claims 33 and the claims dependent thereon for the reasons set forth individually for claim 34, 35, 36, 38, 39, 40, 48, 49, 50, 51, 56, 57 and 64. (Note that claim 76 is identified as rejected with claim 33 on page 8 of the Action, but no further explanation is provided for the rejection of claim 76 as anticipated by Kapp).

Contrary to the Examiner's conclusions regarding claims 33-36, 38-40, 48-51, 56, 57 and 64 under 35 U.S.C. §102(e) over Kapp, Applicant strongly disagrees. The teachings of Kapp alone do not, and cannot, overlap the teachings of the current application. The differences between the teachings lie in the differences in the definition of "new." If one were to rely entirely on a dictionary, the term "new" can mean "recent" or it can mean "novel," and the difference lies in the context. Whether one should rely on a dictionary to define a term or the specification has been the subject of a recent landmark en banc decision by the Court of Appeals of the Federal Circuit. *Phillips v. AWH*, 415 F.3d 1303 (Fed. Cir., June 13, 2005); *Phillips v. AWH*, 363 F.3d 1207 (Fed. Cir. 2004). In the transcript of the case Judge Lourie asked "Are you saying we should rely on a dictionary?" And the reply was "No, you should read the specification first, then the claims. · · · The purpose of the specification is to provide written description and enablement, not to narrow the claims." Transcript from Federal Circuit En Banc

Rehearing on February 8, 2005. In its 56 page en banc decision, CAFC has refocused its approach to claim construction — moving away from extrinsic evidence offered by dictionaries and encyclopedias toward a more detailed analysis of the patent specification. In the process, the majority en banc panel rejected the claim construction approach of *Texas Digital Systems v. Telegenix* (Fed. Cir. 2002) and its progeny.

Under *Phillips*, the specification "necessarily" informs proper claim construction and shapes the meaning of the claims. While both Kapp and Applicant's invention relate to adverse events, Applicant's application specifically relates to identifying "novel" (*i.e.*, patentable) adverse events. The invention is a research tool/business method for researchers to identify patentable information of commercial value. The Kapp invention, on the other hand, is solely related to informing pharmacists and those who prescribe treatments about known adverse events resulting from drug interactions. As described in the Kapp patent (see below), the invention works by scanning known information to see if the patient is likely to have a reaction to the medicine the physician plans to prescribe. The Kapp patent states (paragraph 61) "To detect whether a drug interaction problem exists, the drug interaction analysis sub-module 150 uses the patient medical data, drugs, and the new drug as a search criterion for searching a drug information file 154 and a medical condition file 152. While the medical condition file 152 contains information concerning interactions between drugs and medical conditions, the drug information file 154 contains information concerning a drug-drug interaction or a drug-food interaction." The Kapp patent does not teach or even suggest that the "adverse event" at issue is a patentable event, nor does it suggest that the practitioner would even consider whether the adverse event is patentable. The Kapp abstract states that:

> A pharmacy drug management system provides pharmacy drug management software for patient-specific drug dosing, drug interaction analysis, order generation, and patient data matching. When a drug is added for a patient, the system detects if the drug is a doser drug requiring precise therapeutic dosing and also detects if the drug will cause any drug interaction problems for the patient, reducing the likelihood of clinical misjudgments. The system checks for drug interaction problems resulting from drugs, food allergies, and the medical condition of the patient. An on-screen order may then be generated. A doctor or pharmacist thus is aware of any drug interaction problems before writing an order for the patient. If a selected drug is a doser drug, the system uses phannacokinetic equations specific to the patient data to calculate the appropriate therapeutic dosing parameters.

See also paragraphs 0012 and 0013, wherein the Kapp specification states that the invention provides "a pharmacy drug management system for monitoring and correcting iatrogenic drug illnesses so as to deliver optimum drug therapy to a patient in a managed care environment." Further "the pharmacy drug management system provides patient specific drug dosing, drug interaction analysis, order generation, and patient data matching. The modules provided by the pharmacy drug management software include a drug interaction analysis sub-module, a drug dosing module, an order generation module, and a patient data matching module." While the Kapp module "allows the input of detailed medical history, allergies, diet and prescribed drugs from all physicians being seen by the patient, drugs that are intended to be prescribed, and any non-prescription medications that are being used," the generic information is used in a manner and for a purpose that is quite different and readily distinguishable from Applicant's invention. The features of the Kapp drug interaction analysis sub-module is set forth in paragraph 0013 and the resulting "drug warning" is based upon *current* patient information (drugs being used by patient, condition of patient, etc).

The operation of the Kapp drug interaction analysis sub-model 150 is diagramed in FIG. 6 as described in paragraph 0061, wherein the various current entries of patient medical data is used to determine whether a drug interaction problem exists. "To detect whether a drug interaction problem exists, the drug interaction analysis sub-module 150 uses the patient medical data, drugs, and the new drug as a search criterion for searching a drug information file 154 and a medical condition file 152." Thus, the Kapp specification clearly defines what is meant by "new," and what is not meant by the term. The information being considered in the Kapp method/model is *current* patient information and the "*new*" drug refers to a temporal meaning of the term – as in, newly administered to the patient. Accordingly "new" as used by Kapp in the temporal context has nothing to do with a meaning of novelty.

In marked comparison to Kapp, Applicant's invention as taught by the specification provides a system and methods for screening adverse event information on the basis of "*novelty*" in terms of patentability. At paragraph 0004, Applicant states that "The government has carefully established codes and rules under which, for example in the medical field, manufacturers and/or distributors are required to notify or warn the public of known adverse events which could occur when certain products, including drugs, medicaments and the like, are ingested or used by human or veterinary patients." Thus, the non-temporal meaning of "new," as

novel, is clearly supported in Applicant's specification at least in the Summary at paragraph 0007 "The current invention permits not only ways of screening for new, *previously unrecognized adverse events associated with the use of a product or device*, but also a method, system and device for determining which new adverse events and new uses are "essential" (emphasis added). See also paragraph 0040, "One can use the data from the database to compare to previously known adverse events to determine new adverse event information." And paragraph 0076, "Equipped with the new essential adverse information generated by systems 10, 110 and 210, · · ·."

Applicant describes Essential Adverse Event Information beginning at paragraph 0085. "The final determination of what is "essential" information is determined by a regulatory agency such as the FDA." See paragraph 0086, expressly directing the practitioner to information such as attached Exhibit A. Applicant's "new adverse event information" is "essential," as further defined in paragraph 0087, specifically in terms of proprietary data - as that

> which is of great commercial value since if this information is proprietary, for example patented in the form of a new use, it can be used to exclude potential competitors from selling a product which would require the essential information. In order for a company searching through raw adverse new uses, to maximize profits from such a search, the "essential" new uses should ideally be separated from other new uses. By limiting the protection for such new data, e.g., patenting, and limiting petitions to regulatory agencies to only the "essential" new uses, a company saves time and money by avoiding expending time on adverse event information that has little commercial value.

Applicant further explains at paragraph 0094, that "[h]aving estimated the risk of an adverse event associated with a product, such as a drug, one can determine if the adverse events are essential. Several different criteria can be utilized to determine if the adverse reaction is essential," followed by a listing of non-limiting examples. By comparison, at paragraph 0095, Applicant defines an unnecessary adverse event, as one that "would be an essential adverse event that could be, or could have been, easily avoided. In the list that follows in paragraph 0094, a drug interaction is described as an "unnecessary adverse event" which could have been avoided by withholding one of the interacting drugs. Other such unnecessary adverse events are then listed. Paragraph 0096 describes another type of essential adverse event information, wherein risk "exceeds the benefit." Paragraph 0097 describes a third type of essential adverse event information, wherein "frequency of the adverse event is so high, or the event so severe, that [it

is] a significant health concern or medical management issue" other essential adverse events in this category include marked abnormalities in laboratory values, vital signs, EKG, and seizures. Paragraph 0098 describes a fourth type of essential adverse event information, that is so well characterized that causation is generally believed to exist, such as those detected in two separate, well-controlled clinical trials, industrial chemicals that are known to cause severe adverse events. See also paragraph 0100 describing another use of Applicant's adverse event model to develop new methods of screening drugs for adverse events.

The Examiner further cited "Analyzing (Therapy coordinator module 128 provides a drug interaction module 150, par 59, Fig 5) the adverse event data to identify new essential adverse events associated with the product or device." However, as noted above because the Kapp model is temporal it looks for recent events, rather than "novel" adverse events, in its algorithm. By comparison, since the goal of Applicant's invention is to search for patentable adverse events. Classen treats recently reported adverse events as "old," since adverse events reported by others are not patentable.

Next the Examiner states "creating at least one essential adverse event information database (database is inherent because a DUE report indicating utilization of a drug can be generated, par 58)." However, Applicant respectfully disagrees that the DUE report meets the requirement for creating an essential adverse event database. Nevertheless, since the Examiner fails to support his assumption with evidence that Kapp teaches "to identify at least one new useful characteristic or use for the product or device responsive to identification of at least one new essential adverse event associated with the product or device," this argument is moot. The later is the crucial and unique part of this step in Applicant's claim. Kapp fails to teach identifying a new useful characteristic or use for the product because the Kapp invention is not a research model or system.

Finally, regarding claim 33, the Examiner states that Kapp teaches "commercializing essential adverse event information . . ." However, Applicant's application defines commercialize as meaning "selling or licensing the proprietary information." (See paragraph 0068) Nowhere does the Kapp system *create* essential adverse event information (since it is not a research instrument). Kapp merely applies new patient information to newly prescribed drugs. There is no essential adverse event information to commercialize in Kapp, because it does not create information to sell. The Kapp system places previously reported adverse event

information in its modules for an entirely different purpose that involves no commercial purpose. Kapp gets this information presumably from pharmaceutical companies, but offers no commercialization, and comprises no proprietary information that may be sold.

In the rejection of claim 34, the Examiner contends that Kapp teaches "accessing the at least one adverse event data source comprising raw data from a plurality of different adverse events." If in fact that is what is taught by Kapp, Applicant respectfully asks the Office to point out one instance in which Kapp uses the term "raw data," because Applicant was unable to find any use of such a term. Nor would one expect Kapp to use such a term because Kapp teaches accessing data from the medical condition file (152) and the Drug Information File (154). However, this data has been previously obtained from other sources, so it has already been processed. Thus, such files cannot be considered "raw data." While the Kapp model does comprise patient information, such information is compiled *before* the drug is prescribed - so it is not adverse event information.

In contrast to Kapp, Applicant defines "raw" in the specification at paragraph 0041.

> By "raw data," as used herein, means data before it is processed and analyzed. For example, the raw efficacy or adverse event data relating to a drug would include all of the collected data, which is linked to individuals who used the drug, or in some instances for a product such as tobacco, for those exposed to the product. This raw data comprises, *e.g.*, the individual's weight, height, race, lab results, medical conditions and length of use or exposure to a product or device. By contrast, "processed data" means analyzed data that has been categorized or qualified to meet the requirements or standards of a particular situation.

Thus, when Applicant's meaning of "raw data" is distinguished from "processed data", it is clear that Applicant's claim 34 is not anticipated by Kapp.

In rejecting claim 38, the Examiner argues that Kapp discloses "further accessing at least one data source comprising information relating to raw commercial or sales data." However, in light of the foregoing explanation of why Kapp fails to teach any use of "raw data," this argument is moot. US Pat. No. 6,584,472, incorporated by reference into Applicant's application, further defines raw data as it pertains to commercial data (col. 12, ln 35) stating the "commercial data" is information pertaining to the ability to profit from the sale or trade (as opposed to the use of) of a product or device." Specifically, as defined, "commercial data is not intended to mean, e.g., what drugs and amounts of drugs a person is taking. Nor is it intended to

mean, e.g., what number or percent of people are taking a drug, such as insulin, as additional information is needed to estimate profitability, such as unit costs, sale prices, competitors, market share, etc."

In rejecting claim 39, the Examiner states that Kapp discloses "further comprising providing the at least one adverse event data source comprising adverse event data gathered from at least 5,000 subjects [par 6]." However, there is no statement by Kapp of how many people *should* be used to determine adverse events, not is it likely to provide such information. Kapp does not teach a system/model for discovering or identifying adverse events as taught by Applicant; rather Kapp merely provides a model for disseminating information to physicians and pharmacists *after* such information is discovered and provided by a third party. No data is created by Kapp from a pool of individuals as a data source.

In rejecting claim 40, the Examiner states that Kapp discloses "further comprising providing the at least one adverse event data source comprising information regarding amount of use of the product or device or duration of exposure to the product or device by each subject." However, while Kapp does reference applying a correct dose, this information is *not* utilized with regard to adverse events, nor would one expect it to be. As Applicant has noted, Kapp does not teach a system for discovering or identifying adverse events; rather the Kapp model is used to disseminate information to physicians and pharmacists *after* the information has been discovered and provided by a third party. Kapp provides a drug dosing module (FIG. 3), but this module is separate and distinct from the adverse event modules 152, 154 (diagram on face of Kapp published application), and nowhere in Kapp are the modules described in use together.

In rejecting claim 48, the Examiner states that "Kapp discloses the essential adverse information is proprietary (Fig 8A, 196)." However, what the Examiner does not point out is that Kapp fails to describe how to obtain "patentable adverse event information," which is an essential element of Applicant's application. Kapp teaches only how to use adverse event information. FIG. 8A makes no mention of "patenting adverse event information" or the use of such patentable adverse event information. Thus Kapp cannot anticipate Applicant's claimed invention which is necessarily based upon "proprietary" adverse event information. See Applicant's specification at paragraphs 0003 and 0069 "in order for adverse event information to be valuable it must be patentable (*i.e.* proprietary)" and "[a]s used herein, proprietary information shall be construed to mean information that is used or intended to be used for

establishing or claiming specific intellectual property rights." Therefore in Applicant's invention, a "proprietary new use" means a new use, in which one has or is seeking intellectual property rights, *i.e.*, a patent. This is neither taught nor suggested by Kapp, meaning that claim 49 is not anticipated by Kapp.

In rejecting claim 49-51 and 56, 57 and 64, the Examiner states that "Kapp discloses a proprietary product or device," that "the product is medicinal," and that "the product is commercially available [par.3]." However, the cited claims depend, directly or indirectly, upon claim 33, and includes the elements set for therein. Kapp's software/computer system could not be created by Applicant's method of claim 33; rather the computer is Kapp's proprietary product. Claim 33 is distinguished from Kapp for the foregoing reasons, as supported, at least, by Applicant's paragraphs 0003, 0071 and 0084, and therefore, dependent claims thereon cannot be anticipated by Kapp.

As is well established in patent law, a rejection for anticipation cannot be based upon part of a reference, while selectively omitting required elements of the cited reference that would otherwise clearly distinguish that part of the reference from Applicant's invention. To be anticipating, it is well established law that a cited reference must disclose each and every element of the claimed invention. For the reasons stated above, Kapp's published application fails to teach each and every element of Applicant's claims cited by the Examiner. As a result, Kapp does not and cannot anticipate Applicant's invention. Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. §102(e) of Applicant's claimed invention be withdrawn.

Regarding Rejections under 35 U.S.C. §103

The Examiner has rejected claims 37, 43, 45, 65, 69, 73-75, 77 and 80 under 35 U.S.C. §103 as unpatentable over Kapp. Specifically with regard to claims 37, 69, 73,,74, 79, 80, the Examiner has stated that, although Kapp fails to teach one data source comprising information relating to patents and patent applications, official notice is taken that patents and patent applications are a well known and expected data source "because [they] include novel and non-obvious sources of data." As a result, the Examiner argues that "The ordinary skilled artisan would have been motivated to improve Kapp's invention by considering data sources included in

patents and patent applications for the purpose of asserting the current state of the art." Respectfully, however, Applicant traverses such a circular and unfounded argument.

Kapp's invention is intended to provide safety information to physicians and pharmacists. Thus, Kapp's invention has value because the FDA requires manufacturers to provide/disclose all important safety information to the public. However, it is not at all obvious why one skilled in the art would be motivated to spend the money and time to search additional databases to find additional information that the FDA has previously determined was *not* important enough to be of value to physicians. Since for the above stated reasons Kapp is distinguished from Applicant's invention, and since the Examiner has not supplemented the gaps pointed out above with regard to the differences between Kapp and Applicant's claim 33, Kapp's drug safety model does not, and cannot, obviate Applicant's claimed invention anymore than it could anticipate it.

In rejecting claim 77, the Examiner states that "Kapp discloses using the method to develop at least one essential proprietary new method of screening a product or device for safety (par 10)." However, Kapp's invention is not a research tool, and simply recognizing that patents and patent applications are novel and non-obvious sources of data does not provide a patentable method of screening drugs for adverse events. On what basis does the Examiner conclude, other than his own unsupported assumptions, that because patenting provides protection of intellectual property it would have been obvious for someone to develop Kapp's invention into a completely different algorithmic model that would become the research tool provided by Applicant's invention? In particular, no motivation is suggested by Kapp, absent an alternative reference to fill in the fact that, as recognized by the Examiner, Kapp fails to disclose any step of commercializing the method, let alone provide or even suggest a step to protect "the intellectual property rights of newly identified product information." Kapp's invention is not a research tool. Kapp did attempt to patent his invention for all that it encompassed and for all that, as an inventor, he was entitled to. Yet, Kapp does not provide an algorithm that would develop patentable safety information because it fails to discover patentable adverse event information.

The difference between Kapp' invention and Applicant's invention is more than simply recognizing that patents and patent applications are novel and non-obvious sources of data. Moreover, the difference is more than the simple fact that the Kapp algorithm offers no option, disclosure or suggestion of commercialization. There is a far greater difference between the data sources used by each invention, and whether the data source proves temporally "new"

information, or whether the data source used is novel information from preexisting sources and content. It is not obvious how, without significantly more information, impermissibly drawn from Applicant's invention, that one would know how to apply Kapp's disclosure and, given its limitations, still be able to use it to protect intellectual property rights.

Re: rejection of claim 41 over Kapp and Mueller

The Examiner has further rejected claim 41 under 35 U.S.C. §103(a) as unpatentable over Kapp, in further view of US Patent No. 6,323,242 (Mueller). In making this rejection, the Examiner has relied upon Kapp for the reasons of record to teach Applicant's claims 33 and 39 upon which claim 41 depends. In doing so, however, the Examiner has reiterated the limitations Kapp, and its inability to provide post-exposure adverse event data over a time course of selected increments. To compensate for that gap, the Examiner has added the product post-exposure adverse event data over a time course of selected increments provided by Mueller, and when combined with Kapp, for example, as motivated in a patient with a long history of substance abuse, argues that Applicant's claim 41 would be obvious.

In response, Applicant's point to the fact that Mueller teaches a method for treatment of neuropsychiatric symptoms or disorders emanating from primary brain or systemic impairments includes administration of an effective dose of a dopamine, serotonin, and norepinephrine reuptake inhibitor to a human in need of such treatment. As a result, not only would Mueller's drug dosage schedule for therapeutic treatment not be combined with Kapp's algorithm to produce the algorithm of Applicant's model, it is unlikely that one of ordinary skill (as defined above) would even understand Mueller. To assume that Mueller and Kapp could be combined in the field of research tools or business methods is possible only if one relies entirely upon Applicant's claim 41 to provide the blueprint by which one could take information in Mueller completely out of context and combine it into a patent disclosure from a completely different field. Yet patent law prohibits such a hindsight application of Applicant's claim, solely to direct combinations of this type that would never even be considered by one of skill in the algorithms used in the field of Applicant's invention.

Undoubtedly in almost every issued patent that teaches a therapeutic regime, there are provided dosages, tolerance levels and time courses after which the drug wears-off and must be re-administered. However, recognizing that such information is required by the FDA for every

drug administered to a human, while perhaps an advantage that Kapp failed to recognize, does not, even if combined with Kapp, provide the "at least one adverse event data source comprising information regarding product post-exposure adverse event data, which is recorded in selected time increments" of Applicant's claim 41. Mueller teaches the treatment of neuropsychiatric symptoms in a patient. It fails to add a data source at all; offering only data regarding therapeutic methods and the effect of when the administered drug wears off. Nor does Mueller add "product post-exposure adverse event data" within the meaning of Applicant's invention – which has been fully explained above. Simply because a drug wears off, is not a post-exposure adverse event. While perhaps relevant to safety considerations, wearing-off is an expected result at some time point after any single dose of a drug is metabolized in the patient's system, but the time to do so does not necessarily create an adverse event per se. As a result, for the foregoing variety of reasons, the Mueller treatment methods cannot be combined with the Kapp algorithm; and even if it were, Kapp fails to obviate the underlying claims 33 and 39 for Applicant's reasons of record. Mueller fails to supply information that would be useful if one were trying to adapt Kapp to provide the system and methods taught by Applicant. Consequently, Kapp cannot be bolstered by Mueller to obviate Applicant's claim 41, even if Kapp is supplemented by Mueller's time course. Accordingly, Applicant respectfully asks for withdrawal of the rejection of claim 41 under 35 U.S.C. §103(a) as unpatentable over Kapp, in further view of Mueller.

Re: rejection of claim 42 over Kapp and Park

The Examiner has rejected the claim corresponding to claim 42 (now in Applicant's new claims) under 35 U.S.C. §103(a) as unpatentable over Kapp, in further view of US Publ. No. 2002/0082930 (Park). In making this rejection, the Examiner has relied upon Kapp for the reasons of record to teach Applicant's claim 33 upon which the claim corresponding to claim 42 depends. In doing so, however, the Examiner has reiterated the limitations Kapp, and its inability to provide a commercializing step. To compensate for that gap, the Examiner has added Park's teaching of commercialization, further comprises selling, leasing or licensing the newly identified product information, thereby asserting that if Kapp and Park were to be combined, together they would render Applicant's claim corresponding to claim 42 obvious.

In response, Applicant's point to the fact that Park, in fact, teaches a method of marketing over a network of interconnected computing/communication devices, *e.g.*, the Internet,

specifically comprising the steps of providing a web-site that is identified as specific to a market sector. By comparison, neither Kapp nor Applicant's invention is taught as being used for commercialization over the Internet. Thus, to reject Applicant's claim corresponding to claim 42 on this basis requires selecting only the commercialization aspect of Park, while selectively ignoring that such commercialization *requires* marketing over the Internet. If Park taught that marketing over the Internet is only one option of commercialization, the teachings of the reference may be separated to provide a marketing aspect to Kapp's invention. But since every aspect of Park relies exclusively on commercialization via the Internet, and Kapp suggests neither commercialization, nor use of the Kapp drug safety model over the Internet, it would be impermissible to suggest that the art motivates such a combination. To do so would require impermissibly using Applicant's invention in hindsight as a blueprint to select only the commercial aspect of Park, while selectively ignoring the underlying requirement that Park's commercialization must be accomplished over the Internet.

To support the rejection, the Examiner has relied upon paragraph 0128 of Park to teach "selling, leasing or licensing the newly identified product information · · · for the purpose of providing assistance to the vendor to sell the product." Paragraph 0128, indeed, states that "information assists the vendor in selling more product or services." However, "information" in this case refers to "the most 'correct' and 'useful' information, that is to say information which mostly closely approximates the consumer's exact needs for information so as to effectively evaluate purchases." Applicant respectfully asks the Office to explain how information regarding the selection of a purchase is in any way related to Kapp's safety model or Applicant's research tool – neither of which have anything to do with a purchase of any kind. The purpose of Park is to establish a vendor's "superbrand" in the mind of the consumer as the most trustworthy source of the information based upon complete and extensive information about the customer's purchasing needs (paragraph 0127) and describes a balance regarding the "use of data between the conflicting interests of the consumer and the vendor."

No conflict exists between the consumer and the vendor in either Kapp's or Applicant's invention, and in fact there is no vendor in either case. Moreover, neither Kapp's nor Applicant's invention would have utility as, or in conjunction with, a marketing tool over the Internet. To assume that Park and Kapp could be combined into a research tool or business methods is possible only if one relies entirely upon Applicant's claim corresponding to claim 42

to provide the blueprint by which one could take information in Park completely out of context and combine it with a published disclosure teaching marketing over the Internet. Yet patent law prohibits such a hindsight application of Applicant's claim, solely to direct combinations of this type that would never even be considered by one of skill in the algorithms used in the research tool taught by Applicant's invention.

As a result, for the foregoing variety of reasons, Park's method for marketing a product over the Internet cannot be combined with the Kapp algorithm; and even if it were, Kapp fails to obviate the underlying claims 33 and the claim corresponding to claim 42 for Applicant's reasons of record. Park fails to supply a method for commercialization that would be useful if one were trying to adapt Kapp to provide the system and methods taught by Applicant. Consequently, Kapp cannot be supported by Park to obviate Applicant's claim corresponding to claim 42, even if Kapp is supplemented by Park's Internet marketing method. Accordingly, Applicant respectfully asks for withdrawal of the rejection of the claim corresponding to claim 42 under 35 U.S.C. §103(a) as unpatentable over Kapp, in further view of Park.

Re: rejection of claims 46, 47, and claims corresponding to 66, 67, and 81-83 over Kapp and Schea

The Examiner has rejected claims 46, 47, and claims corresponding to 66, 67, and 81-83 (now found in Applicant's new claims) under 35 U.S.C. §103(a) as unpatentable over Kapp, in further view of US Pat. No. 5,181,394 (Schea). In making this rejection, the Examiner has relied upon Kapp for the reasons of record to teach Applicant's claim 33 upon which each of the identified claims 46, 47, and the claims corresponding to 66, 67, and 81-83 indirectly depend. In doing so, however, the Examiner has reiterated the limitations of Kapp, and its inability to provide a commercializing step. To compensate for that gap, the Examiner has added Schea's teaching of "identifying the at least one use of the product or device as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device" as taught in the background of the Schea patent (col. 1, ln. 40- col. 2, ln. 6).

In response, Applicant's point to the fact that Schea, in fact, teaches freeze protective units suitable for use in the transport and storage of products such as those biologically active proteins which may be susceptible to irreversible physicochemical alteration upon freezing.

Schea teaches no method for identifying a "new use of the product or device as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device." In fact, Schea offers no information what-so-ever that would supplement Kapp to provide "a *restricted* use" of Applicant's claimed invention, wherein such *restricted* use is avoided by giving a drug to a person who is likely to have an adverse event. As a result Applicant asks the Office to provide support for this argument, since it is unclear to Applicant how the cited passage in Schea - column 1, line 40- column 2, line 6 – relates to Applicant's claimed *restricted* use. Schea states in the cited passage that "potential risks are, of course, exacerbated by the fact that visual inspection of, *e.g.*, a unit dosage vial containing a solution of therapeutic protein is insufficient to reveal that the product has undergone freezing at some time during its transport or storage · · · ." Applicant's claims 46, 47, and claims corresponding to 66, 67 and 81-83 all relate to *restricted uses*, regardless of the commercial availability of the product or device, the subgroup selected, whether the new adverse event comprises a drug interaction or exposure to a product or device.

Without additional explanation, Schea's freeze protective units appear to be so far afield from either Kapp's invention or Applicant's research tool, that even if impermissively led by Applicant's claims as a blueprint to combine the cited reference, one of ordinary skill would neither make such a combination, nor understand why the Office has found motivation for such a combination. And even if combined by some perverse logic, Kapp in combination with Schea still fails to provide any teaching or suggestion of Applicant's claims 46, 47, and claims corresponding to 66, 67 and 81-83 – each of which define *restricted uses* as stated therein. Consequently, Kapp cannot be supported by Schea to obviate Applicant's claims 46, 47, and claims corresponding to 66, 67 and 81-83, even if Kapp is supplemented by Schea's teaching of freeze protective units transporting and storing protein products. Accordingly, Applicant respectfully asks for withdrawal of the rejection of claims 46, 47, and claims corresponding to 66, 67 and 81-83 under 35 U.S.C. §103(a) as unpatentable over Kapp, in further view of Schea.

Re: rejection of claims 52 and 53, and apparently corresponding to 67, over Kapp and Socinski

The Examiner has rejected claims 52 and 53 under 35 U.S.C. §103(a) as unpatentable over Kapp, in further view of US Pat. No. 6,696,924 (Socinski). In making this rejection, the

Examiner has relied upon Kapp for the reasons of record to teach Applicant's claim 33 upon which the identified claims 52 and 53 depend. In doing so, however, the Examiner has reiterated the limitations Kapp, and its inability to provide that when the subject product is a medical drug it is generic. To compensate for that gap, the Examiner has added Socinski's teaching of "a generic drug" (col. 3, lns. 35-45). Similarly, the Examiner appears to have also rejected claim 67 at page 14 of the Office Action on a similar basis, although the rejection of claim 67 is unclear. Applicant will assume that the Examiner meant to refer to claim 67 in citing the addition of Socinski's Fig. 8A, step 150 regarding drug interactions.

In response, Applicant's point to the fact that Socinski, in fact, teaches a hand-held computer able to supply information to a user about allopathic and homeopathic drugs, nutrients and supplements, minerals and the effects of combinations thereof when taken together. The cited paragraph in the summary describes that the Socinski database in the hand-held computer includes "known pharmaceutical and homeopathic drug companies, a listing of their respective drugs and a description of each drug, the description of each drug including its generic name, common indications and usage, clinical pharmacology, clinical studies, contraindications; warnings, precautions, adverse reactions, dosages; administration; how supplied, animal toxicology; patient information, cautions, side effects and any nutrient or mineral interactions." Neither Kapp nor Applicant teach a hand-held computer, and while Kapp addresses the safety consideration of drug interactions, and there could be motivation to combine Kapp with Socinski, such a combination is unrelated to the invention in Applicant's claims 52 and 53, and corresponding to claim 67, unless the claims are read completely out of the context of Applicant's specification.

Claims 52 and 53, and corresponding to claim 67, are directly or indirectly dependent upon Applicant's claim 33 or new claim 201, and for the reasons of record that Kapp alone fails to teach Applicant's invention. Nothing added by the addition of Socinski changes the fact that Kapp still fails to render claim 33 (or claim 201) obvious. Kapp's invention fails to identify new (meaning novel) adverse events, nor does it identify proprietary (*i.e.*, patentable) new uses based previously gatherer drug interaction data, wherein the new use is avoiding the drug interaction. Because Kapp's invention relies on obtaining information from others, under the Kapp model, once one is notified of a drug interaction, then avoiding such an adverse drug interaction would

be obvious – and thus, avoiding the drug interaction discovered by others is not a patentable event.

Consequently, Kapp cannot be supported by Socinski to obviate Applicant's dependent claims 52 and 53, and corresponding to claim 67, because Socinski adds nothing to Kapp to teach the underlying claim 33 (or claim 201). Therefore because Kapp fails to teach claim 33 (or claim 201), regardless of the addition of Socinski, claims 52 and 53 are not unpatentable because the base upon which they depend, has not been proven unpatentable. Accordingly, Applicant respectfully asks for withdrawal of the rejection of claims 52 and 53, and corresponding to claim 67, under 35 U.S.C. §103(a) as unpatentable over Kapp, in further view of Socinski.

Re: rejection of claims 54, 55, 58, 59, 70-72, and 78 over Kapp and Farmer

The Examiner has rejected claims 54, 55, 58, 59, and corresponding to 70-72 and 78 (now found in Applicant's new claims) under 35 U.S.C. §103(a) as unpatentable over Kapp, in further view of US Publ. No. 2003/000496 (Farmer). In making this rejection, the Examiner has relied upon Kapp for the reasons of record to teach Applicant's claims 33, 49 and corresponding to 69, upon which the identified claims 54, 55, 58, 59 and corresponding to 70-72 and 78 depend. In doing so, however, the Examiner has reiterated the limitations Kapp, and its inability to provide information when the product is non-medical. It is logical that Kapp fails to provide for non-medical applications since, in fact, Kapp is purely related to medical safety, *i.e.*, avoiding adverse drug interactions,. As a result a publication for a non-medical product or device could be added to Kapp only by selectively disregarding essentially the entire purpose for the Kapp invention – which would be motivated only if one were to impermissibly use Applicant's claims 54, 55, 58, 59, and corresponding to 70-72 and 78 in hindsight as a blueprint for the combination. Nevertheless, in an effort to compensate for the fact that Kapp fails to teaching the use of data relating to a non-medical product or device, the Examiner has added Farmer's teaching of "non-medical product information" (paragraph 10).

In response, Applicant's point to the fact that Farmer, in fact, teaches integrated, data-centric hazard communication system comprising an authoring module and a means for disseminating hazard information about a material and its components, decomposition products and related materials. See paragraph 10. Neither Kapp nor Applicant teach anything related to such a such an integrated, data-centric hazard communication system, and even if combined with

Kapp, such a combination is unrelated to the invention in Applicant's claims 54, 55, 58, 59, and corresponding to 70-72 and 78, unless the claims are read completely out of the context of Applicant's specification.

Kapp discloses an invention to inform pharmacists and physicians about drug adverse event information that it receives from other sources (primarily the manufacturers). Kapp is not a research tool and provides no reason to develop safety data sheets. Rather, Kapp takes data from the manufacturer, (*i.e.*, the product data sheet) and transmits it to the pharmacist or physician. This is a marked distinction from Applicant's invention –see, for example, paragraph 0101, where the advantage are described regarding a competitor when an adverse event information is covered in a patent (*i.e.*, proprietary adverse event), and inclusion of this adverse event is provided in a product data safety sheet or the like (claim corresponding to claim 70).

Regarding the claim corresponding to claim 78, the Examiner states that Kapp discloses "using the method to develop at least one essential proprietary new method of screening a product or device for safety." Yet, regardless of whether or not Kapp's invention is patentable for what it does teach (informing pharmacists and physicians about adverse drug events based upon information received from other sources (primarily the manufacturer)), it does not and cannot lead to the development of patentable information. As noted, Kapp's invention is not a research tool, nor is it intended to develop new (as in novel) methods of screening products for safety. Instead, Kapp merely takes data from the manufacturer, (*i.e.*, the product data sheet) and transmit it to the pharmacists. Such methods of passing information *as provided* to a third party is unrelated to the research tool defined by Applicant's invention.

Moreover, Farmer's paragraph 10 continues by describing other critical elements of the Farmer invention - "[w]ithin the authoring module there is a means for decompiling material data, a means for associating the decompiled data with hazard information, and a means for recompiling material data associated with hazard information to provide hazard information about the material, its components, decomposition products of the material, and substances related to the material." Applicant's make no reference to the use of a means for decompiling material data, a means for associating the decompiled data with hazard information, and a means for recompiling material data associated with hazard information. As a result, it would be impermissible to combine on those portions of Farmer that would be selected only if one relies entirely upon Applicant's claimed invention to provide the blueprint by which one could take

information in Farmer completely out of context while ignoring other required aspects of the Farmer invention within the same cited paragraph. Yet patent law prohibits such a hindsight application of Applicant's claim, solely to direct combinations of this type that would never even be considered by one of skill in using the research tool taught by Applicant's invention.

Claims 54, 55, 58, 59 and corresponding to 70-72 and 78 are dependent upon Applicant's claims 33, 49 and corresponding to 69, and for the reasons of record that Kapp alone fails to teach Applicant's invention, nothing added by the addition of Farmer changes the fact that Kapp still fails render claims 33, 49 and corresponding to 69 obvious. Consequently, Kapp cannot be supported by Farmer to obviate Applicant's dependent claims 54, 55, 58, 59 and corresponding to 70-72 and 78 because Farmer adds nothing to Kapp to teach the underlying claims 33, 49 and corresponding to 69. Therefore because Kapp fails to teach claims 33, 49 and corresponding to 69, regardless of the addition of Farmer, claims 54, 55, 58, 59 and corresponding to 70-72 and 78 are not unpatentable because the base upon which they depend, has not been proven unpatentable. Accordingly, Applicant respectfully asks for withdrawal of the rejection of claims 54, 55, 58, 59 and corresponding to 70-72 and 78 under 35 U.S.C. §103(a) as unpatentable over Kapp, in further view of Farmer.

Re: rejection of claim 75 over Kapp

The Examiner has rejected the claim corresponding to claim 75 (now found in Applicant's new claims) under 35 U.S.C. §103(a) as unpatentable over Kapp, in further view of the Official Notice taken. In making the rejection, the Examiner takes Official Notice that "using the method to produce lower costs for development of the product or device, or quicker time to market, or an expected higher return for development costs associated with the product or device, or any combination thereof" is well known in the art and represent a direct result of obtaining patent protection. Yet the claim corresponding to claim 75 is not an independent claim. In fact, it is a dependent claim containing therein the defining steps of the independent claim on which it depends. Consequently, such a rejection is moot in light of the Applicant's reasons of record.

Applicant has shown that Kapp *alone* cannot render any portion of Applicant's claimed invention unpatentable, and without additional support, the Office cannot simply assume facts on the basis of Official Notice in an attempt to reject Applicant's claim corresponding to claim 75.

Therefore because Kapp fails to teach Applicant's independent claims, regardless of the addition of facts assumed from Official Notice, the claim corresponding to claim 75 is not unpatentable because the base upon which it depends, has not been proven unpatentable. Accordingly, Applicant respectfully asks for withdrawal of the rejection of the claim corresponding to claim 75 under 35 U.S.C. §103(a) as unpatentable over Kapp, in further view of the Notice taken.

Re: rejection of the claims corresponding to claims 60, 62, 63 and 84 over Kapp and Foote

The Examiner has rejected the claims corresponding to the claims corresponding to claims 60, 62, 63 and 84 under 35 U.S.C. §103(a) as unpatentable over Kapp, in further view of US Pat. No. 6,715,796 (Foote). In making this rejection, the Examiner has relied upon Kapp for the reasons of record to teach Applicant's claim 33 upon which the identified claims corresponding to claims 60, 62, 63 and 84 depend. In doing so, however, the Examiner has reiterated the limitations Kapp, and its inability to disclose "labeling notifying a user of at least one new essential adverse event for the product or device." To compensate for that gap, the Examiner has added Foote "for the purpose of providing instructions regarding usage of the drug" (col. 3, ln. 35-45).

In response, Applicant's point to the fact that Foote, in fact, teaches a method for preparing both main label and warning label portions for a container useful in dispensing drugs by a pharmacist, wherein the label utilizes a multi-part blank which can be fed into a computer driven printer, and when printed will contain all of the parts needed for a complete set of labels. The claim corresponding to claims 60, 62, 63 and 84, are directly or indirectly dependent upon Applicant's claim 33 or new claim 201, and for the reasons of record that Kapp alone fails to teach Applicant's invention. Nothing added by the addition of Foote changes the fact that Kapp still fails to render claim 33 (or claim 201) obvious. Kapp's invention fails to identify new (meaning novel) adverse events, nor does it identify proprietary (*i.e.*, patentable) new uses based previously gatherer drug interaction data, wherein the new use is avoiding the drug interaction. While Kapp's invention may be patentable for what it teaches, as noted above it does not lead to the development of patentable information because Kapp merely transmits information as received from other sources (primarily the manufacturer) to inform pharmacists and physicians about adverse drug events.

However, Kapp is not about creating labels, and the ability to create a label would have no bearing on the Kapp invention. Contrary to the Examiner's conclusion that it would be useful to add a label to notify a user of at least one new essential adverse event for the product or device misses the point of the Kapp invention altogether. If there were only a single possible adverse event for each drug, such proposed labeling might be effective, but in fact, Kapp has found the need for an entire database to provide such warnings. What then would the proposed label say – see database? No a label on the product or device identifying each adverse event would meet the need, requiring an entire database to cover all of the possible adverse interactions. Moreover, the Kapp invention does not proprietary information as required in the underlying claims upon which the cited claims are based, nor can Kapp claim patentable information for Applicant's reasons of record.

Consequently, Kapp cannot be supported by Foote to obviate Applicant's dependent claims corresponding to claims 60, 62, 63 and 84 that are directly or indirectly dependent upon Applicant's claim 33 or new claim 201, because Foote adds nothing to Kapp to teach the underlying claim 33 (or claim 201). Therefore because Kapp fails to teach claim 33 (or claim 201), regardless of the addition of Foote, claims corresponding to claims 60, 62, 63 and 84 are not unpatentable because the base claims upon which they depend, have not been proven unpatentable. Accordingly, Applicant respectfully asks for withdrawal of the rejection of claims corresponding to claims 60, 62, 63 and 84 under 35 U.S.C. §103(a) as unpatentable over Kapp, in further view of Foote.

Re: rejection of claim 61 over Kapp and Schea, in further view of Farmer or Foote

The Examiner has rejected the claim corresponding to claim 61 (now found in Applicant's new claims) under 35 U.S.C. §103(a) as unpatentable over Kapp and Schea, in further view of Farmer and/or apparently Foote based upon the explanation found at page 17 of the Office Action. In making the rejection, the Examiner asserts that Kapp and Schea together fail to disclose "labeling notifying a user of at least one new essential adverse event for the product or device." Applicant agrees with the Examiner that the cited references, even in combination, fail to teach Applicant's claimed invention. Nevertheless, in an effort to compensate for that failure, the Examiner has added Farmer and Foote to include labeling (col. 1, ln. 20-35).

Yet the claim corresponding to claim 61 is no more taught by the addition of Farmer and/or Foote, than it is by Kapp alone or Kapp combined with Schea. In fact, the claim corresponding to 61 is a dependent claim, containing therein the defining steps of the independent claim on which it depends. Consequently, such a rejection is moot in light of the Applicant's reasons of record regarding the cited references, even if viewed an combination.

Applicant has shown that neither Kapp *alone*, nor Kapp in combination with Schea, can render any portion of Applicant's claimed invention unpatentable. Moreover, neither Farmer, nor Foote provides the information needed to supplement the deficits remaining from Kapp combined with Schea, with regard to their ability to teach Applicant's claimed invention. Therefore, because Kapp combined with Schea fails to teach Applicant's independent claims, regardless of the addition of the cited references, the claim corresponding to claim 61 is not unpatentable because the base upon which it depends, has not been proven unpatentable. Accordingly, Applicant respectfully asks for withdrawal of the rejection of the claim corresponding to claim 61 under 35 U.S.C. §103(a) as unpatentable over Kapp and Schea, in further view of Farmer and/or Foote.

Thus, having reviewed each of the Examiner's arguments as relating to the cited references, even when viewed in combination, Applicant respectfully submits that there is no prior art that teaches Applicant's invention *as claimed*. Applicant's invention is neither anticipated nor obvious in view of any cited reference or any combination thereof. It is respectfully submitted, therefore, that all of Applicant's pending claims are in condition for allowance, and Applicant respectfully requests that allowance be granted at the earliest date possible. Should the Examiner have any questions or comments regarding Applicant's amendments or response, the Examiner is asked to contact Applicants undersigned representative at (215) 988-2700.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0573. A duplicate copy of this Amendment and Response is enclosed.

Respectfully submitted,

Date: January 30, 2006

Evelyn H. McConathy
Registration No. 35,279
DRINKER BIDDLE & REATH LLP
One Logan Square, 18th and Cherry Streets
Philadelphia, PA 19103-6996
Tel: (215) 988.3361
Fax: (215) 988.2757